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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,484

07/21/2005

Yoshihisa Nishibe

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34375 7590 10/21/2008

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,484	<b>Applicant(s)</b> NISHIBE ET AL.	
	<b>Examiner</b> Jeffrey T. Palenik	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5 Aug 2008</u> .                                              | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Receipt is acknowledged of Applicants' Amendments and Remarks filed 17 March 2008. The Examiner acknowledges the following:

Claim 1, alone, has been amended and contains no new matter.

Support for the amendments is found in the previously presented claim 1.

Claims 4-9 remain presently withdrawn from consideration.

Thus, claims 1-3 still represent all claims currently under consideration.

### **INFORMATION DISCLOSURE STATEMENT**

One new Information Disclosure Statement (IDS), filed 5 August 2008, is acknowledged and has been considered.

### **WITHDRAWN OBJECTIONS/REJECTIONS**

#### **Objection to the Specification**

Applicants' amendments to the Abstract of the Invention render the objection to the Specification moot. Thus, said objections have been withdrawn.

### **MAINTAINED REJECTIONS**

The following rejections are maintained from the previous Office Action dated 18 December 2007:

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Karlsson et al. (U.S. Patent Publication 2002/0065256).

Claim 1 is drawn to a composition of matter comprising a ciclesonide-containing sterile aqueous suspension. Claim 2 further limits the composition of claim 1 by requiring that the composition also contain hydroxypropyl methylcellulose (HPMC). The composition is taught by Karlsson et al. at claims 7, 9, and 10. Claim 10 teaches a thickening agent which is further defined as including hydroxypropyl methylcellulose (see [0040] and [0041]).

Therefore each and every limitation is met by the reference.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (U.S. Patent Publication 2002/0065256) in view of the Material Safety Data Sheet (MSDS) for Metolose 60SH.

Karlsson et al. teaches the ciclesonide and HPMC suspension, as described above. However, Karlsson does not teach the specific grade of HPMC (HPMC 2910) as cited in claim 3. Per Applicant's specification, the claimed HPMC 2910 is also known industrially as Metolose 60SH. Shin-Etsu Co. produces the HPMC of the present invention and provides an MSDS which further provides a Recommended Use for Metolose 60SH as a thickening agent. Therefore,

Since the ingredient of the composition is the chemically the same, it follows that particular grade of HPMC used is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to employ the optimal grade hydroxypropyl methylcellulose within the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed

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parameters, optimization of this ingredient would have been obvious at the time of Applicant's invention.

#### **RESPONSE TO ARGUMENTS**

Applicants' arguments with regard to the rejection of claims 1 and 2 under 35 USC 102(b) as being anticipated by Karlsson et al., and with regard to the rejection of claims 1-3 under 35 USC 103(a) as being unpatentable over Karlsson et al., have both been fully considered, but neither are persuasive.

Applicants argue that Karlsson teaches away from the claimed subject matter since Karlsson's methods do not appear teach or suggest sterilizing an aqueous ciclesonide-containing suspension.

In response, the Examiner respectfully submits that Applicants' amendments to independent claim 1 do not add further clarity to the claimed subject matter. The first amendment merely changes the location of the term "sterile" within the preamble. The second amendment made to the claim adds the phrase "a ciclesonide-containing aqueous suspension" to a limitation which had been previously deemed a product-by-process limitation. Per MPEP §2113, product-by-process limitations hold no patentable weight. Thus, regardless of how the instantly claimed ciclesonide-containing aqueous suspension is made sterile, the fact still remains that a sterile ciclesonide-containing aqueous suspension results. Thus, independent claim 1 continues to recite a composition of matter comprising a ciclesonide-containing sterile aqueous suspension. Karlsson expressly teaches a sterile pharmaceutical formulation comprising a glucocorticosteroid which is sterile in an aqueous

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suspension (Claim 7). Ciclesonide is an expressly taught glucocorticosteroid (see [0016]).

Claims 9 and 10 expressly teach the inclusion of a thickening agent. Hydroxypropyl methylcellulose is an expressly taught thickening agent (see [0041]).

Thus, for these reasons, Applicants' arguments are found unpersuasive. Said rejections are maintained.

All claims remain rejected; no claims are allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615